CLAIMS

1. Use of a humanised or human chimeric monoclonal antibody of which the glycan structure of the Fc domain of the antibody corresponds to a biantennary type, with short chains, low sialylation, non-intercalating terminal mannoses and GlcNAc of the attachment site, and low fucosylation, for the preparation of a drug intended for the treatment of patients homozygous for phenylalanine in position 158 of CD16 (FCGR3A-158F homozygotes) or patients heterozygous for valine/phenylalanine in position 158 of CD16 (FCGR3A-158V/F).

2. Use of a composition of antibodies defined in claim 1, which composition has a concentration of over 60%, preferably over 80% for the forms G0 + G1 + G0F + G1F, given that the forms G0F + G1F are lower than 50%, preferably lower than 30%, for the preparation of a drug intended for the treatment of patients homozygous for phenylalanine in position 158 of CD16 (FCGR3A-158F homozygotes) or patients heterozygous for valine/phenylalanine in position 158 of CD16 (FCGR3A-158V/F).

3. Use according to either of claims 1 or 2, characterised in that the patients are homozygous for phenylalanine in position 158 of CD16 (FCGR3A-158F homozygotes).

4. Use according to any of the previous claims, characterised in that the treatment with the antibodies currently available has failed in the patients, or the patients have experienced adverse effects.

5. Use according to any one of the previous claims, characterised in that the dose of said antibody

administered to the patient is 50 times lower, preferably 100 times lower than a dose of an antibody of the same specificity but of different glycosylation or produced in a CHO line.

6. Use according to one of the previous claims, characterised in that the antibody is directed against a non-ubiquitous antigen present in healthy donor cells, in particular an anti-Rhesus of the human red blood cell, or an antigen of a pathological cell or of an organism pathogenic for humans, in particular against an antigen of a cancer cell or infected by a virus.

7. Use according to one of the previous claims for the preparation of a drug intended for the treatment of cancers and infections by pathogens.

8. Use according to one of claims 1 to 5 for the preparation of a drug intended for the treatment of diseases escaping the immune response, in particular selected from haemolytic disease of the newborn, Sezary Syndrome, chronic myeloid leukaemias, chronic lymphoid leukaemias (CLL-B), solid tumours, breast cancer, conditions related to the environment in particular affecting people exposed to polychlorinated biphenyls, infectious diseases, in particular tuberculosis, chronic fatigue syndrome (CFS), parasitic infections such as, for example, schistosomas or paludism, in particular in pregnant women, and viral infections.

9. Use according to one of claims 1 to 5 for the preparation of a drug intended for the treatment of conditions in which the antigen is poorly expressed.

10. Use according to one of claims 1 to 5 for the preparation of a drug intended for the treatment of cancers of positive HLA class-II cells, B-cell lymphomas,

acute B-cell leukaemias, Burkitt's syndrome, Hodgkin's lymphoma, myeloid leukaemias, chronic B-cell lymphoid leukaemias (CLL-B), non-Hodgkin's T-cell leukaemias and lymphomas and chronic myeloid leukaemias.

11. Use according to one of claims 1 to 10, characterised in that the antibody is an anti-HLA-DR or an anti-CD20.

12. Use according to one of claims 1 to 10, characterised in that the antibody is selected from anti Ep-CAM, anti HER2, anti CD52, anti HER1, anti GD3, anti CA125, anti GD, anti GD2, anti CD-23 and anti Protein C; anti-KIR3DL2, anti-EGFR, anti-CD25, anti-CD38, anti-CD30, anti-CD33, anti-CD44, inhibitor-specific anti-idiotypes, for example, coagulation factors, and anti-virals.

13. Use according to one of claims 1 to 12, for the production of a drug intended to induce enhanced cytotoxicity by ADCC of type FcγRIII (CD16), greater than 60% compared with the same antibody produced in CHO or with a homologous product available on the market, which drug is useful in particular in the treatment of cancer and infections of patients homozygous for phenylalanine in position 158 of CD16 (FCGR3A-158F homozygotes) or patients heterozygous for valine/phenylalanine in position 158 of CD16 (FCGR3A-158V/F).

14. Use according to one of claims 1 to 13, for the production of a drug intended to induce enhanced cytotoxicity by ADCC of type FcγRIII (CD16), greater than 100% when said antibody is at a concentration of 10 ng/ml compared with the same antibody produced in a CHO line or with a homologous antibody available on the market.

15. Use according to one of claims 1 to 14, for the production of a drug intended to induce the secretion of

at least one type of cytokine by a type of effector cell of the immune system expressing CD16, above 50%, 100% or preferably above 200% compared with the same antibody produced in a CHO line, selected from IL-1, IL-4, IL-12, IL-18, IL-21, IL-2, IL-3, IL-5, IL-6, IL-7, IL-8, IL-9, IL-10, IFNα, IFNβ, TNFα, TGFβ, IP10 and TNF, IFNγ.

Figure 1

ADCC en présence de cellules effectrices (PBMC) de différents donneurs de sang et d'immunoglobulines polyvalentes	ADCC in the presence of effector cells (PBMC) of different blood donors and polyvalent immunoglobulins
% de lyse	% lysis
No. du donneur	Donor number

Figure 2

ADCC induit par les anti-Rhésus D sur NK de donneurs de phénotype CD16 F-F 158	ADCC induced by anti-Rhesus D on NK of donors of phenotype CD16 F-F 158
% de lyse	% lysis
Ac concentration	Ab concentration

Figure 3

ADCC induit par les anti-Rhésus D sur NK de donneurs de phénotype CD16 V-V 158	ADCC induced by anti-Rhesus D on NK of donors of phenotype CD16 V-V 158
% de lyse	% lysis
Ac concentration	Ab concentration

Figure 4

Activation de Jurkat CD16 F-158 par les anti-D (T125) exprimés dans YB2/0 et CHO.	Activation of Jurkat CD16 F-158 by anti-D (T125) expressed in YB2/0 and CHO
Taux IL2	IL2 level
Concentration d'anticorps	Antibody concentration

Figure 5

Activation de Jurkat CD16 V-158 par les anti-D (T125) exprimés dans YB2/0 et CHO.	Activation of Jurkat CD16 V-158 by anti-D (T125) expressed in YB2/0 and CHO
Taux IL2	IL2 level
Concentration d'anticorps	Antibody concentration

Figure 6

Activation de Jurkat CD16 F-158 par les anticorps anti-HLA-DR exprimés dans CHO et YB2/0.	Activation of Jurkat CD16 F-158 by anti-HLA-DR antibodies expressed in CHO and YB2/0.
Taux IL2	IL2 level
ng/ml d'anticorps	ng/ml of antibodies

Figure 7

Activation de Jurkat CD16 V-158 par les anticorps anti-HLA-DR exprimés dans CHO et YB2/0.	Activation of Jurkat CD16 V-158 by anti-HLA-DR antibodies expressed in CHO and YB2/0.
Taux IL2	IL2 level
Concentration d'anticorps	Antibody concentration